No benefit seen with rituximab for chronic fatigue syndrome

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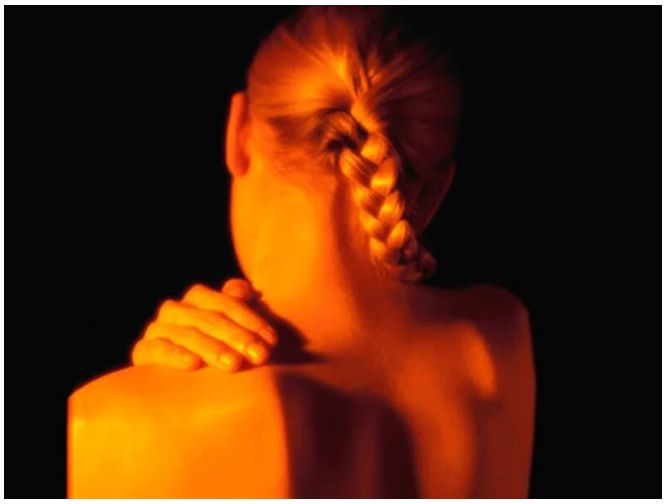

(HealthDay)—In patients with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), B-cell depletion using several infusions of rituximab over 12 months is not associated with clinical improvement, according to a study published online April 2 in the *Annals of Internal Medicine*.

Øystein Fluge, M.D., Ph.D., from Haukeland University Hospital in Bergen, Norway, and colleagues examined the effect of the monoclonal anti-CD20 antibody rituximab versus placebo on ME/CFS. One hundred fifty-one patients aged 18 to 65 years were randomly assigned to treatment with either two infusions of rituximab, 500 mg/m² of body surface area, followed by four maintenance infusions at three, six, nine, and 12 months, with a fixed dose of 500 mg (77 participants) or placebo (74 participants).

The researchers found that the overall response rates were 35.1 and 26.0 percent in the placebo and rituximab groups, respectively (difference, 9.2 percentage points; 95 percent confidence interval, ?5.5 to 23.3 percentage points; P = 0.22). There was no difference in fatigue score over 24 months or any of the secondary end points in the treatment groups. Serious adverse events were reported by 26.0 and 18.9 percent of patients in the rituximab and placebo groups, respectively.

"This study highlights the importance of randomized and blinded clinical trials with a placebo group, especially in diseases that lack specific and sensitive biomarkers, have limited possibilities for objective end points, and rely mainly on self-reported symptom scores," the authors write.

Several authors hold patents related to treatment of ME/CFS.

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